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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,435	11/30/2004	Joseph P. Orban III	2823	3071
Covidien 60 Middletown Avenue North Haven, CT 06473			EXAMINER WOO, JILLAN W	
			ART UNIT 3773	PAPER NUMBER
			MAIL DATE 05/20/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/516,435

Applicant(s)

ORBAN III ET AL.

Examiner

Julian W. Woo

Art Unit

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2009.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
4a) Of the above claim(s) 16-22 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-15, 23 and 24 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 9, 2009 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-15, 23, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to base claims 1 and 23, it is not certain whether "staples" are considered structural parts of the invention, since the support structure is said to contain wound closure material "until penetration by the staples." That is, is there a point at which the staples become a part of the invention?

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-10, 13-15, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giampapa (5,201,728). Giampapa discloses the invention substantially as claimed. With respect to claims 1, 3, 4, 5, 10, 13-15, 23, and 24, Giampapa discloses, at least in figures 2, 6, and 7 and in col. 3, line 67 to col. 4, line 22; a support structure including an annular ring (10) having an outer annular wall with a diameter, an inner annular wall spaced a radial distance inward of the outer inner wall and defining a space (14, 16), a upper wall, a lower wall; the outer and inner annular walls and the upper and inner walls defining a reservoir, and a therapeutic material releasable from the reservoir; the support structure containing the therapeutic material until contact with another object or at more intentional pumping or dispensing of the therapeutic material (see col. 5, lines 31-44) ; where the annular ring has a circular cross-sectional profile, where the structure includes at least one removable support spoke (filaments of capillary mesh 17) integrally connected to an extending diametrically across the inner annular wall and a central hub having a central axial opening formed therethrough (a central cell or opening in the capillary mesh), where the annular outer

and inner walls comprise a rigid material (e.g., silicone or polytetrafluoroethylene [sic]); where the annular ring comprises a plurality of interstitial spaces (between filaments of element 17 (where the filaments contact element 10) configured and adapted to allow staple legs to pass through (if so desired) and a plurality of cartridge orientation members or nubs (at the intersections of the filaments of element 17)

With respect to base claim 1 and claims 6-9, Giampapa discloses therapeutic materials releasable from the reservoir, but do not specifically disclose wound closure materials as claimed. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made, to apply the wound closure materials as claimed, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

With respect to claim 2, Giampapa discloses the invention substantially as claimed, but does not disclose the diameters of the outer and inner annular walls as claimed. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to size the annular walls as claimed, since such modifications would have involved mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

Note: The introductory statement of intended use ("for use in conjunction with a circular endoscopic stapling instrument having a staple cartridge assembly and an anvil assembly, the staple cartridge assembly having at least one annular arrangement of staple slots and staples positioned in the slots, wherein the support structure maintains

a resulting anastomotic lumen in an open condition") has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over the devices of Giampapa, which is capable of being used as claimed if one desires to do so.

6. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Giampapa (5,201,728) in view of Pilliar (3,855,638). Giampapa discloses the invention substantially as claimed, but does not disclose that the rigid material comprises stainless steel or titanium. Pilliar teaches, at least in col. 2, lines 61-68 and col. 3, lines 24-35; an implantable, porous material comprising stainless steel or titanium. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Pilliar, to apply porous stainless steel or titanium as the rigid material in Giampapa. Such a material is biocompatible, would promote tissue ingrowth, and provide a structure with mechanical strength, if so desired, for support of regenerated tissues.

7. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Giampapa (5,201,728) in view of Schmitt et al. (3,739, 773). Giampapa discloses the invention substantially as claimed, but does not disclose that the rigid material comprises a bioabsorbable material. Schmitt et al. teach, at least in col. 6, lines 1-63; an implantable, porous material (PGA) that is bioabsorbable. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Schmitt et al. to apply a porous bioabsorbable material as the rigid material in Giampapa. Such a material would promote tissue ingrowth and provide for the healing

and strengthening of tissues without having an inconvenient, non-absorbable component left in a patient's body.

Response to Amendment

8. Claims 1-15, 23, and 24 are hereby rejected with new grounds under 35 U.S.C. 112, 2nd paragraph.

Applicant's arguments filed on January 30, 2009 and regarding the rejections based on the Giampapa reference have been fully considered but they are not persuasive. Applicant contends that Giampapa's pod "is not a reservoir." First, Merriam-Webster's Collegiate Dictionary, 10th edition, defines "reservoir" to include "a place where something is kept in store," "a part of an apparatus in which a liquid is held," a "supply," or a "store." So given the broadest reasonable interpretation of "reservoir," the pod of Giampapa is indeed a reservoir, in that it is a part of the apparatus in which biologically active materials are held in, supplied from, or stored in pores (superficially and internally) of the pod. Even without a dome, Giampapa's pod may still be considered a reservoir in that any and all bio-acting agents are held in or dispensed from the pod and that the pod itself may be treated with bio-acting agents (see col. 4, lines 7-22). Furthermore, the dome is simply an independent and separable reservoir that supplies agents to the pod—another reservoir.

With respect to the argument that Giampapa is not "configured and adapted to substantially overlie the at least one annular arrangement of staples of the staple cartridge assembly": Applicant is reminded that the recitation that an element is

"configured to" or "adapted to" perform a function only requires the ability to so perform. *In re Hutchison*, 69 USPQ 138. Giampapa's device, with or without the dome, is indeed adaptable to the function as claimed. Even with a dome, it would have been obvious to one having ordinary skill in the art to size the dome, among other components of the support structure, for use with a stapler as claimed. Moreover, Applicant has not claimed or defined the structure of a stapler or staples in such a way that would deny the use of Giampapa's device with the stapler or staples.

Applicant also argues that "capillary mesh or a portion thereof" (element 17) of Giampapa's device is not removeable. First, on the contrary, Giampapa discloses, at least in figures 2 and 6, the integration of element 17 and pod 10. That is, element 17 is a separate structure fastened to or welded to pod 10 at assembly of the support structure. Thus, at least at assembly of the parts, element 17 is separable, i.e., removeable, from the pod. Moreover, it has been held that constructing an integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

Finally, Applicant argues that Giampapa, among the prior art of record, does not disclose or suggest that the support structure contains wound closure material "until penetration by the staples." The Applicant is arguing the intended use of the claimed apparatus (i.e., the support structure is to be used with staples). Applicant is reminded that it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2

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USPQ2d 1647 (1987). As shown in the rejection above, at least the apparatus of Giampapa satisfies the claimed structural limitations.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ayer et al. (4,200,098) and Theeuwes (4,203,439) teach reservoirs.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773